

EXHIBIT E

From: Peterson, Liane M.
Sent: Tuesday, May 24, 2022 8:02 PM
To: Gocha, Alan J.
Cc: Ellis, Nicholas J.
Subject: FW: TRUTEK CORP. v. BLUEWILLOW BIOLOGICS, INC.
Attachments: 2021-10-28 JOINT DISCOVERY PLAN.doc; 2021-10-23 Letter from Dr. E. Lemmo.pdf

Importance: High

Redacted

-----Original Message-----

From: shk@shk-dplc.com <shk@shk-dplc.com>
Sent: Monday, October 25, 2021 11:48 PM
To: Peterson, Liane M. <LPeterson@foley.com>
Subject: Re: TRUTEK CORP. v. BLUEWILLOW BIOLOGICS, INC.
Importance: High

** EXTERNAL EMAIL MESSAGE **

Good evening Liane:

Resending!

Stan

On 2021-10-25 10:14, Peterson, Liane M. wrote:

> Stan,
>
> Can you please resend the attachments? There was nothing attached to
> your email.
>
> Liane
>
> -----Original Message-----

> From: shk@shk-dplc.com <shk@shk-dplc.com>
> Sent: Monday, October 25, 2021 10:04 AM
> To: Peterson, Liane M. <LPeterson@foley.com>
> Subject: TRUTEK CORP. v. BLUEWILLOW BIOLOGICS, INC.
> Importance: High
>
> ** EXTERNAL EMAIL MESSAGE **
>
> TO: Liane M. Peterson, Esq. <lpeterson@foley.com>
> FROM: Stanley H. Kremen, Esq. <shk@shk-dplc.com>
> SUBJECT: TRUTEK CORP. v. BLUEWILLOW BIOLOGICS, INC.
> DATE: October 25, 2021
>
> --
> Dear Liane:
>
> Pursuant to our telephone conversation this morning, I am sending you
> Plaintiff's draft for our joint discovery plan. I am also attaching a
> letter from one of our technical experts in this matter.
>
> Please get back to me with your revisions.
>
> Thank you for your kind attention.
>
> Stan
> (732)593-7294
>
>
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Edward A. Lemmo, Ph.D.
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October 23, 2021

Mr. Stanley H. Kremen, Esq.
4 Lenape Lane
East Brunswick, New Jersey 08816

Dear Mr. Kremen,

You engaged my services as a technical expert consultant in the matter of Trutek Corp. ("Trutek") v. BlueWillow Biologics, Inc. ("BlueWillow"), currently in litigation in federal court in the Eastern District of Michigan, Southern Division, Case No. 2:21-cv-10312.

At your request, I reviewed United States Patent No. 8,163,802 (hereinafter the '802 Patent) titled, "Electrostatically Charged Multi-Acting Nasal Application Product, and Method," that was issued to Ashok Wahi on April 24, 2012. I believe that BlueWillow formerly did business as Nanobio Corporation ("Nanobio"). It is my understanding that BlueWillow manufactured and sold a product named "Nanobio Protect," which Trutek alleges that it infringes "at least claims 1, 2, and 7" of the '802 Patent. It is also my understanding that BlueWillow is actively developing nanoemulsion vaccines to be administered nasally.

In addition, I reviewed many journal articles on the subjects of nanoemulsions and vaccines. Among other documents, I also reviewed United States Patent Numbers 8,226,703; 8,703,164; 9,131,680; 9,144,606; 9,492,525; 9,561,271; 10,206,996; and 10,525,121, all assigned to Nanobio. Further, I reviewed United States Patent Numbers 7,314,624; 9,974,844; and 10,138,179, all assigned to Regents of the University of Michigan. I concluded that the University of Michigan patents relate to the work being performed at BlueWillow. They were authored by inventors associated with the Nanobio patents. It is my belief that these patents as well as other publications by the inventors relate to nasally administered nanoemulsion vaccines under development by BlueWillow. It is my understanding that government approved trials of one or more of the BlueWillow vaccines may be currently ongoing.

Having compared independent claims 1 and 2 of the '802 Patent (owned by Trutek) with the patents and other publications describing the work at BlueWillow, it is my opinion that the BlueWillow vaccines probably infringe on these claims of the '802 Patent.

The claimed formulations of both Trutek and BlueWillow are administered nasally. Both formulations would form a thin film in the nasal passages. The Trutek formulation exhibits an electrostatic charge. Nanoemulsions represent the basis of the BlueWillow vaccines, and nanoemulsions also exhibit electrostatic charges. As with the Trutek patent, nanoemulsions

would attract harmful particulate matter electrostatically and render it harmless. This would be the case even if the BlueWillow vaccines produce an immune response in subjects by an entirely different mechanism from that of the '802 Patent formulation or from that of BlueWillow's "Nanobio Protect" product.

Having reviewed the relevant literature and the patents issued to both Trutek and BlueWillow, as well as the related University of Michigan patents, there appears to be a need to further elucidate the composition of the delivery system mechanism of the BlueWillow formulations relative to the Trutek patent claims. Regardless of the active component (biotherapeutic, vaccine, medication, *etc.*) being delivered, the issue relates primarily to the delivery system.

The use of an intranasal delivery system for administration of an active component or biotherapeutic, is at the core of this matter. How these patents compare based on composition of matter, needs to be analyzed in discovery so that a clear comparison can be made. The formulations need to be understood, and the vaccine products need testing. Regardless of theoretical considerations, without such an analysis, infringement of the claims of the '802 patent by the BlueWillow vaccines cannot be definitely established.

With both the Trutek and BlueWillow formulations, the useful purpose of the technology is to act as a means of defense against a microbial contaminant (viral or bacterial agent) by setting up a barrier mechanism. In both cases, the delivery system helps to prevent or minimize the exposure risk to the body of a viral load by administering an active agent in the nasal passage. Both Trutek and Blue Willow have made claims for an intranasal delivery system, and both have made claims for the use of Benzalkonium Chloride within their delivery system.

Having researched the patents' claims of both Trutek and Blue Willow and noting the patents and public announcements made by BlueWillow regarding development and marketing of various 'nano-emulsion vaccines' for use against different strains of Influenza, Anthrax, Covid, *etc.*, it is necessary to determine if the delivery systems are infringing. In both cases, the purpose of the Trutek and Blue Willow research, development, and patents is to prevent the severity of illness resulting from exposure to microbial agents.

It is my recommendation that discovery reveal the composition of the BlueWillow nasal vaccine formulations, and that such formulations be tested to determine whether there is actual infringement of the claims of the '802 Patent. It is also important to gain knowledge as to whether BlueWillow (or associated entities) have applied for government approvals for/or conducted clinical trials of their nasally administered nanoemulsion vaccines.

Respectfully submitted,



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EDUCATION

Ph.D. Nutrition Science, Rutgers University, New Brunswick, NJ (1979)
M.S. Nutrition Science, Rutgers University, New Brunswick, NJ (1977)
B.S. Chemistry, St. Francis College, Brooklyn, NY (1973)

EXECUTIVE TRAINING COURSES

Executive Leadership Program, Princeton, NJ
Time Management Skills, Teaneck, NJ
Media Communication Skills, New York City, NY

EMPLOYMENT EXPERIENCE

2007-Present	Consumer Healthcare Corporate Consultant Self-employed Consultant - Consumer Healthcare
2005-2007	BioBalance Corporation , New York, NY Vice President, Product Development Person primarily responsible for investigating its probiotic product PROBACTRIX™ to be used for treating pouchitis and other gastrointestinal disorders. Probiotic products are an optional alternative to the probiotic Lactobacillus acidophilus. In charge of all scientific product evaluation conducted at company headquarters.
1999-2005	Wyeth Consumer Healthcare , Leonia and Madison, NJ Vice President, Product Development Division of American Home Products Formerly Whitehall-Robbins Consumer Healthcare Managed product development for SOLGAR®, and contributed towards CENTRUM®, and CALTRATE®, brands. Responsible role in scientific affairs and new business

development opportunities. Further, responsible for evaluation of acquisition of new business entities.

1992-1999

General Nutrition Centers, Inc., Pittsburg, PA
Director, Nutritional Sciences

Analyzed safety of amino acid products for presentation to the FDA and FTC and other U.S. government agencies. Evaluated and made recommendations regarding nutritional and homeopathic products. Performed quality assurance activities related to label claims and product safety. Responsible for introduction of the new PRO-PERFORMANCE sports nutrition product line into the GNC retail marketplace.

In 1993, for Quigley Corporation, I evaluated the safety and efficacy of Cold-EEZE® zinc lozenges to be used to shorten a common cold as a possible line of homeopathic products exclusively marketed by GNC.

1989-1992

Pall Biomedical Products, Glen Cove, NY
Marketing Manager

Responsible for marketing activities of Intravenous filtration devices, and Heat and Moisture exchange respiratory products. Wrote all scientific evaluation documents related to Heat and Moisture Exchange respiratory product for presentation to anesthesiologists regarding prevention of injury from patients breathing cold dry gas during surgery. Developed scientific presentations, videos, and product marketing material for use by healthcare professionals.

1984-1989

ICN Pharmaceuticals, Costa Mesa, CA
Director of Nutritional Technology

Faraday Laboratories Division

Product development of nutritional supplements for use by chiropractic and alternative health practitioners throughout the United States and Canada. Product brands included Nutridyn® and Sivad Bioresearch®. Responsible for new product development, wrote technical literature, and prepared and delivered scientific educational presentations to practitioners at chiropractic colleges and chiropractic meetings.

1976-1977	Pharmacia Laboratories , Piscataway, NJ Clinical Trials Coordinator Assisted veterinarian in analysis of equine blood samples. Performed evaluation analysis of HEALON® products comprising hyaluronic acid, and their effect on tissues.
<u>CORPORATE CONSULTING EXPERIENCE</u>	
2011	Matrixx Initiatives, Inc. , Princeton, NJ Scientific Affairs Consultant Performed research associated with ZICAM® oral zinc product. Provided guidance for coordinating research trials. Managed human efficacy clinical trials.
1998-1999	Church & Dwight , Princeton, NJ Scientific Advisor Evaluated consumer healthcare products. Explored and determined market for magnesium based organo-metallic agents for use in dietary supplements.
1998-1999	IVC Industries , Freehold, NJ IVC is a contract manufacturer of generic vitamins. Responsible for new product development. Assisted the marketing staff with product label claims.
1996	Nutrition 21 , Purchase, NY Company is a supplier to GNC. Performed consulting work regarding their products.
1996	Nutramerica , Lincoln Park, NJ Technical advisor for the development of a dietary supplement product line.

CORPORATE CONSULTING EXPERIENCE (continued)

1996 **American Vitamin**, Ramsey, NJ
Company is a contract manufacturer. Performed new product development and assistance with evaluation of raw materials from India.

COLLEGE TEACHING EXPERIENCE

2013-2018 **Touro College**, New York City, NY
Taught in nursing school. Courses included pathophysiology, genetics, anatomy and physiology and tutored microbiology

2008-2014 **University of Medicine & Dentistry of New Jersey (UMDNJ)**, Newark, NJ
Taught innutrition program. Courses included general chemistry, anatomy and physiology, biochemistry, and microbiology.

1977 and **New York University**, New York, NY

2000-2003 Taught in graduate nutrition program, vitamin and mineral metabolism

2011-2012 **Cedar Crest College**, Allentown, PA
Taught courses in nutritional biochemistry and metabolism.

1984-1989 **University of New Haven**, West Haven, CT
Taught graduate level course in vitamin and mineral nutrition.

1974-1984 **Brooklyn College, CUNY**, Brooklyn, NY
Assistant Professor
Taught nutrition courses to pre-medical and nutrition students.

1973-1977 **Rutgers University**, Piscataway, NJ
Taught general biology lab and mineral metabolism.